UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/666,863 | 09/17/2003 | **Steven Walak** | 10123/00401 | 8458 |

7590 03/20/2008

Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

| EXAMINER | |
|---|---|
| WYSZOMIERSKI, GEORGE P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1793 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 03/20/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/666,863
Filing Date: September 17, 2003
Appellant(s): WALAK ET AL.

Oleg F. Kaplun
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed February 26, 2008 appealing from the Office action mailed August 27, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

This appeal involves claims 1-23.

Claims 24 and 25 have been withdrawn from consideration as not directed to the elected invention.

**(4) Status of Amendments After Final**

The amendment after final rejection filed on November 27, 2007 has not been entered.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

A substantially correct copy of appealed claims 1-23 appears on pages 13-15 of the Appendix to the appellant's brief. The minor errors are as follows: In line 4 of claim

1 of the Claims Appendix, the phrase “when deployed within the body” should appear after “phase”, as indicated in the listing of claims as filed July 9, 2007.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 5,514,115 | FRANTZEN et al. | 05-1996 |
| 5,964,770 | FLOMENBLIT et al. | 10-1999 |
| 6,923,829 | BOYLE et al. | 08-2005 |

WO 02/36045 A2, published 10 May 2002

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

**A)** Claims 1-8, 15-19 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. (Frantzen) or over WIPO publication 02/36045 (WIPO ‘045).

Both Frantzen and WIPO ‘045 disclose medical devices (e.g. stents and catheters) made of Nitinol alloys and including portions that are in a martensitic state and portions in an austenitic state; see Frantzen column 2, line 31 thru column 4, line 26, or WIPO ‘045 page 8, lines 9-14 and page 10, lines 8-20. With respect to claim 2, any interface between the two such portions in the prior art meet the limitations of this claim, i.e. any such area can be designated as a "transition portion" as recited in appealed claim 2. With respect to claims 6 and 7, note Frantzen column 3, lines 1-3. With respect to claims 8, 15, 18 and 19, the product-by-process limitations in these

claims do not define a patentable product over those described in the prior art absent evidence that the actual products are different from the prior art products in some manner; see *In re Thorpe* (227 USPQ 964, Fed.Cir. 1985) and *In re Marosi* (218 USPQ 289, Fed.Cir. 1983).

The prior art does not specifically recite the conditions regarding strain that the prior art devices are exposed to or the stability of the martensitic phase when deployed within a body. However, because the prior art devices are both made of the same materials as the claimed devices and are intended for use in substantially the same manner, it is a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention. Thus, a prima facie case of obviousness is established between the disclosures of Frantzen et al. or WIPO '045 and the presently claimed invention.

**B)** Claims 2, 9-13, 20 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. or WIPO '045, as above, either of which in view of Flomenblit et al. (Flomenblit).

Like Frantzen and WIPO '045, Flomenblit is directed to medical devices such as stents including both martensitic and austenitic portions. With respect to claim 2, Flomenblit column 4, lines 23-29 indicate that it was known in the art, at the time of the invention, to construct such devices having the limitations as recited in the instant claim. With respect to claims 9-13, 20 and 21, Flomenblit column 6, lines 58-67 indicates it was conventional in the art to employ Nitinol alloys including small amounts of one or

more additional materials (besides Ni and Ti) as required by the instant claims. The precise manner by which these additional materials have come to be present in such devices (e.g. by ion implantation as recited in several of the claims on appeal) is seen as a product-by-process limitation, and therefore does not define a patentably distinguishable product over those in the prior art absent evidence that the actual products of the invention are different from the prior art products in some manner; see *In re Thorpe* (227 USPQ 964, Fed.Cir. 1985) and *In re Marosi* (218 USPQ 289, Fed.Cir. 1983).

Thus, the disclosure of Frantzen et al. or WIPO '045, together with the teachings of Flomenblit et al., would have taught devices as presently claimed to one of ordinary skill in the art.

**C)** Claims 1, 3-8, 14-19, 22 and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (Boyle).

Boyle discloses implantable medical devices made of nitinol, portions of which are in an austenitic phase and portions in a martensitic phase. With respect to claims 8, 15, 18 and 19, the product-by-process limitations in these claims do not define a product patentably distinct from the products of the prior art references for reasons as stated supra. With respect to claims 14 and 23, Boyle column 9, lines 20-28 indicate that different portions of the material have different chemical compositions, as required by the claims on appeal.

The prior art does not specifically recite the conditions regarding strain that the prior art devices are exposed to or the stability of the martensitic phase when deployed in a body. However, because the prior art devices are both made of the same materials as the claimed devices and are intended for use in substantially the same manner, it is a reasonable assumption that these parameters would also be the same or nearly so in the prior art and the claimed invention. Thus, a prima facie case of obviousness is established between the disclosure of Boyle et al. and the presently claimed invention.

**D)** Claims 2, 9-13, 20 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. in view of Flomenblit et al.

Like Boyle, Flomenblit is directed to medical devices such as stents including both martensitic and austenitic portions. All aspects of Flomenblit as described in subsection (B) supra apply equally as well in this instance. Thus, the combined disclosures of Boyle et al. and Flomenblit et al. would have taught the present invention to one of ordinary skill in the art.

**(10) Response to Argument**

Appellant's arguments can be divided along two main lines: a) that the prior art does not disclose any relationship between strain and the placement of martensitic and/or austenitic portions of the prior art articles as set forth in appealed claim 1, and b) that the actual arrangements of martensitic and/or austenitic portions in the prior art

articles are not in accord with what is recited in appealed claim 16. These issues, as well as a brief discussion of the Flomenblit reference, will be addressed in turn.

**A)** The claimed limitations regarding strain levels and the prior art--

Appellant contends that the recitation of "high strain portions and lesser strain portions" in claim 1 on appeal distinguishes the invention from the prior art, i.e. that neither Frantzen nor Boyle relate any positioning of austenitic or martensitic portions of their respective devices to the level of strain that these portions will undergo during use of such devices. While on the surface Appellant's arguments appear valid, they are irrelevant to an analysis of the appealed claims for the following reasons. Claim 1 recites a device including high strain and lesser strain portions "...wherein the high strain portions are to be subjected to levels of strain during use increased with respect to strain levels in the lesser strain portions" [emphasis added].

It is on this basis that Appellant's argument must fail. It is not possible to know beforehand what amount of strain a given device (or any portion of such a device) will undergo at some future time. The claims do not define that any portion of the inventive devices has undergone any particular amount of strain, either in numerical terms or relative to the amount of strain that a different portion of the device has undergone. Rather, the claims indicate that at some time unknown, a portion of the claimed device will be subjected to a level of strain that is increased with respect to some level of strain in another portion of the device. If one had a device as claimed in front of them, and one were asked what portion(s) of the device were to be subjected to what levels of strain, the answer would not be knowable absent more information. In this sense,

devices which comprise a metallic element and which include a portion stabilized in a martensitic phase and a portion which is in an austenite phase (such as the devices of Frantzen, WIPO '045, or Boyle) fall within the scope of the invention because it would be possible to subject the former portion to more strain than the latter portion.

Appellant states in the Brief that high strain portions of an element are easily locatable via deformation analysis as is extremely well-known in the art. The examiner does not dispute that many methods are well-known in the art of measuring strain in an element, either after it has occurred or while it is occurring. But that is not what claim 1 on appeal says. What claim 1 defines is a device having certain portions that will in the future be subjected to different levels of strain. The examiner's position is that prior art devices in which one of skill in the art could easily subject certain portions to differing levels of strain (such as the devices of Frantzen, WIPO '045, or Boyle) render claim 1 unpatentable.

**B)** The placement of austenite and martensite phases in the prior art--

Appellant argues in the Brief that the disclosures of Frantzen, WIPO '045, and Boyle do not disclose structures in accord with what is defined in appealed claim 16. The examiner respectfully disagrees. Specifically, Frantzen column 3, lines 16-30 describes embodiments in which a portion is in a stable martensite phase at body temperature, as required by claim 16. The only two phases described by Frantzen are austenite and martensite, and thus logically the other portion of the Frantzen device (the part that is not martensite) would be austenite, again as required by claim 16.

Turning to WIPO '045, page 10 of this document describes how a superelastic grade of nitinol is in its austenitic phase at body temperature, while a plastically deformable grade of nitinol is in a martensitic phase at the use temperature. Then, page 11, lines 16-27 describe an embodiment which includes plastically deformable material overlying superelastic material. This is analogous to the superelastic austenitic core and the martensitic surface material as recited in claim 16.

The Boyle patent does not appear to disclose any specific embodiments with the superelastic core and martensitic surface as claimed. However, one of the main concepts of the Boyle disclosure is that one can form a pattern in a deposited material (preferably nitinol; see Boyle column 7, lines 10-14). This pattern can be produced by localized heat treatment of the material to form localized martensitic regions; see the paragraph overlapping columns 8-9 of Boyle. It would then be a trivial matter to select particular portions subjected to the treatment so that a surface portion is martensitic and the core portion austenitic, as required by appealed claim 16.

**C)** The Flomenblit patent and various dependent claims--

Appellant has not separately argued any of the dependent claims, nor has appellant directed any specific arguments with regard to the Flomenblit patent, other than stating that all of the claims to which Flomenblit applies are dependent on either claims 1 or 16 and should be allowed for the same reasons as the independent claims. The examiner's position is that Flomenblit discloses subject matter relevant to several of the claims on appeal as set forth in the rejections, supra.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/George Wyszomierski/
Primary Examiner
Art Unit 1793

Conferees:

/Roy King/

Supervisory Patent Examiner, Art Unit 1793

/Gregory L Mills/

Supervisory Patent Examiner, Art Unit 1700